OAH Docket No. 11-0900-17002-1
Governor's Tracking No. AR 047

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH
Public Health Laboratory Division

In the Matter of the Adopted Rules of the Minnesota Department of Health Governing Accreditation of Environmental Laboratories;
Minnesota Rules, Chapter 4740

ORDER ON REVIEW OF RULES UNDER MINNESOTA STATUTES, SECTION 14.26

The Minnesota Department of Health's Public Health Laboratory Division ("Department" or "Agency") is seeking review and approval of the above-entitled rules, which were adopted by the agency without a hearing. Review and approval is governed by Minn. Stat. § 14.26. On July 20, 2006, the Office of Administrative Hearings received the documents that must be filed by the agency under Minn. Stat. § 14.26 and Minn. R. 1400.2310. Based upon a review of the written submissions and filings, and for the reasons set out in the Memorandum which follows,

IT IS HEREBY ORDERED:

1. The agency has the statutory authority to adopt the rules.

2. The rules were adopted in compliance with all procedural requirements of Minnesota Statutes, chapter 14, and Minnesota Rules, chapter 1400, with the exception of one harmless error, as set forth in the Memorandum below.

3. The following provisions of the adopted rules are **DISAPPROVED** as not meeting the requirements of Minnesota Rules, Part 1400.2100, items D and E: rule parts 4740.2050, subps. 1(F), 9(A), and 13(B); 4740.2060, subp. 3(B); 4740.2065, subp. 7; 4740.2070, subp. 10(A) and (B); 4740.2075, subps. 2 and 3; 4740.2099, item C; and 4740.2100, subp. 9(E). All other rule parts are approved.

4. Pursuant to Minnesota Statutes, section 14.26, subdivision 3(b), and Minnesota Rules, part 1400.2300, subpart 6, the rules will be submitted to the Chief Administrative Law Judge for review

Dated: August 4, 2006

s/Barbara L. Neilson

BARBARA L. NEILSON
Administrative Law Judge

MEMORANDUM

Pursuant to Minnesota Statutes, Section 14.26, the agency has submitted these rules to the Administrative Law Judge for a review as to legality. The rules adopted by the Office of Administrative Hearings[1] identify several types of circumstances under which a rule must be disapproved by the Administrative Law Judge or the Chief Administrative Law Judge. These circumstances include situations in which a rule was not adopted in compliance with procedural requirements unless the judge finds that the error was harmless in nature and should be disregarded; the rule is not rationally related to the agency's objectives or the agency has not demonstrated the need for and reasonableness of the rule; the rule is substantially different than the rule as originally proposed and the agency did not comply with required procedures; the rule grants undue discretion to the agency; the rule is unconstitutional[2] or illegal; the rule improperly delegates the agency's powers to another entity; or the proposal does not fall within the statutory definition of a "rule."

In the present rulemaking process, the Administrative Law Judge has found eleven defects in the rules, one of which is a harmless procedural error. The Administrative Law Judge has also recommended ten technical corrections, as discussed below. The technical corrections do not reflect defects in the rules, but are merely recommendations for clarification to the rules that the Department may adopt if it chooses to do so. All other rule parts are approved.

Defects

Procedural Defect (Harmless Error)

The Administrative Law Judge finds that one harmless procedural error has occurred in this rulemaking process. The Department did not include a section in the Statement of Need and Reasonableness ("SONAR") addressing the "probable costs or consequences of not adopting the proposed rule" as required by Minn. Stat. § 14.131. However, by reading the discussion of the other regulatory factors included in the SONAR, the reader can infer the consequences of not adopting the proposed rules. It is the determination of the Administrative Law Judge that this omission from the SONAR did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process. It therefore constitutes a harmless error under Minnesota Statutes, section 14.26, subdivision (3)(d)(1), and Minnesota Rules part 1400.2100(A).

Defects under Minn. R. 1400.2100, Items D and E

The Administrative Law Judge has identified ten other defects in the rules based upon vagueness or undue discretion. Each of these is discussed below.

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1 Minnesota Rules part 1400.2100.

2 To be constitutional, a rule must be sufficiently specific to provide fair warning of the type of conduct to which the rule applies. *Cullen v. Kentucky*, 407 U.S. 104, 110 (1972); *Thompson v. City of Minneapolis*, 300 N. W.2d 763, 768 (Minn. 1980).

Minn. R. 4740.2050, subp. 1, item F (page 13, lines 20-24 of Revisor's draft dated June 23, 2006)

The agency proposes to add language to its base certification requirements as follows: "If a laboratory fails to submit a renewal application within 90 days before the expiration of certification, the commissioner **may** notify the regulatory authorities that receive data that the laboratory did not apply to renew its certification." (Emphasis added.)

As written, the rule part is unduly vague and grants the Commissioner undue discretion in that it contains no criteria as to how the Commissioner will decide whether or not to notify the regulatory authorities. The proposed rule merely gives the Commissioner the option of notifying the regulatory authorities, and regulated parties have no way of knowing under what circumstances the Commissioner will or will not notify the regulatory authorities. To correct the defect, the Administrative Law Judge recommends that the agency either replace "may" with "shall" so that regulatory authorities are notified in all instances or, in the alternative, include criteria in the rule that the Commissioner will use to decide whether or not notification will occur. Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2050 substantially different than originally proposed.

Minn. R. 4740.2050, subp. 9, item A (page 19, lines 9-14)

The agency proposes to add language to the rule part regarding suspensions as follows: "If a laboratory takes corrective action before the end of the suspension period, certification for the suspended fields of testing or for the base certification and fields of testing **may** be restored if the corrective actions satisfactorily address the deficiencies cited in the notice of suspension." (Emphasis added.)

As written, the rule part is unduly vague and grants undue discretion to the Commissioner because it does not provide adequate guidance to the Commissioner regarding the standard to be used in deciding whether or not to restore the certification once corrective action has been taken to address deficiencies. The agency has indicated that it will restore the certification except when prohibited by a reciprocity agreement. In accordance with the agency's intentions, and to correct the defect, the Administrative Law Judge recommends that the agency amend the rule language as follows or in a similar manner: ". . . base certification and fields of testing ~~may~~ shall be restored if the corrective actions satisfactorily address the deficiencies cited in the notice of suspension, except when contrary to an applicable reciprocity agreement." Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2050 substantially different than originally proposed.

Minn. R. 4740.2050, subp. 13, item B (page 26, lines 15-16)

As written, the rule states that the Commissioner "may" specify an expiration date for a variance granted under this rule part. The language of the rule is unduly discretionary and vague because no standard is specified by which the Commissioner is to determine whether or not to specify an expiration date and regulated laboratories will not necessarily know if or when an approved variance will expire. The agency has indicated that it will specify expiration dates for granted variances except when the EPA has given nationwide approval for the use of a particular method. Accordingly, the agency can correct the defect by amending the language as follows or in a similar manner: "The commissioner ~~may~~ shall specify an expiration date for the variances the commissioner issues." Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2050 substantially different than originally proposed.

Minn. R. 4740.2060, subp. 3, item B (page 30, line 27)

This portion of the proposed rules relates to methods required for certification with respect to the clean water program, the safe drinking water program, the resource conservation recovery program, and the underground storage tank program. The proposed rules outline a procedure for a laboratory to seek approval to use alternative methods and apply for a variance with respect to all of these programs except the safe drinking water program. With respect to the safe drinking water program, the rule indicates that the methods are provided under chapter 4720 and 40 C.F.R. parts 141 and 143, and states that "no alternative methods may be used." The agency's Statement of Need and Reasonableness indicates that this approach was taken "because the applicable federal regulation prohibits approval of method modifications for drinking water analysis."

This language constitutes a defect in the rule because, by foreclosing any consideration of variance requests under the safe water drinking program, it grants the agency discretion beyond what is allowed by applicable law. The Minnesota Administrative Procedure Act accords persons and entities the right to petition an agency for a variance from a rule adopted by the agency as it applies to the circumstances of the petitioner.[3] Although agencies may grant variances based on standards specified in other laws,[4] and the Commissioner here may decide to deny variance requests to use alternative methods under the safe drinking water program based on the current federal regulation prohibiting approval of method modifications, the proposed rule is defective because it has the effect of denying persons regulated by the rule the right to submit a variance request even if the federal regulation is subsequently changed or some other compelling reason exists. This defect can be corrected by deleting item B of subpart 3 and adding new items B – D to that subpart that echo the language used in Subparts 2, 4, and 5 relating to the other programs. Changing the language of the rule in accordance with the recommendation of the Administrative Law

3 *See* Minn. Stat. § 14.055. The proposed rule also appears to be at odds with the broad statement in 4740.2050, subp. 13, of the rules that the Commissioner has authority to grant variances from parts 4740.2010 to 4740.2120.

4 Minn. Stat. § 14.055, subd. 5.

Judge is needed and reasonable, and will not make rule part 4740.2060 substantially different than originally proposed.

Minn. R. 4740.2065, subp. 7 (page 35, lines 2-4)

The agency proposes the following language regarding laboratory standard operating procedure manuals: "The laboratory standard operating procedures manual is subject to approval by the commissioner."

The language of the rule part does not specify the criteria that the Commissioner will consider when evaluating a standard operating procedures (SOP) manual, thereby giving the Commissioner undue discretion in making determinations about SOP manuals. The agency indicated that the other subparts of this rule part, specifically subparts 3 and 8, will form the basis for the Commissioner's evaluation. But the agency also stated that other factors will play a role in the determination, such as the experience of the laboratory staff or the number of laboratory staff members. To correct this defect, the agency must amend the language to identify the factors that will be used in evaluating SOP manuals, preferably including references to subparts 3 and 8 and any other criteria that the Commissioner will use. Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2065 substantially different than originally proposed.

Minn. R. 4740.2070, subp. 10, items A and B (page 39, lines 6 and 20)

The language of subpart 10 addresses the availability of proficiency testing ("PT") samples. Item A states that the Commissioner "may" determine that a PT sample is not available for a particular field of testing if certain circumstances exist, and item B states that the Commissioner "may" request written documentation from the laboratory regarding quality control data if no approved provider has PT samples for a field of testing.

No standards are specified in the rule to govern the exercise of the Commissioner's discretion. The unfettered discretion granted to the Commissioner by this rule language creates a defect in the rules. The defect may be corrected by replacing these two occurrences of "may" with "shall." Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2070 substantially different than originally proposed.

Minn. R. 4740.2075, subp. 2 (page 40, lines 4-5)

The proposed language states that the Commissioner "may" approve a PT provider if the PT provider meets specified criteria, which are recited on pages 40-42.

As written, the language of the rule part requires PT providers to demonstrate that they satisfy a lengthy list of criteria as part of the approval process but then does not require the Commissioner to approve the provider, even if all the criteria are met.

The unlimited discretion granted to the Commissioner to deny approval even where the criteria are met creates a defect in the rules. This defect can be corrected by the agency by changing the word "may" to "shall." Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2075 substantially different than originally proposed.

Minn. R. 4740.2075, subp. 3 (page 42, lines 19-26)

The proposed language states, "Proficiency testing providers that fail to establish or maintain a quality system meeting the requirements of this part are subject to loss of approval by determination of the commissioner. Providers **may** lose approval to supply PT samples for particular fields of testing based upon review of proficiency testing sample data or **may** lose approval as a PT provider for all fields of testing if the PT provider fails to meet the requirements of this part." (Emphasis added.)

Again, the language is vague and grants undue discretion to the Commissioner to determine whether or not to remove a provider from the list of approved PT providers. To correct the defect and also clarify the apparent intent of the rule, the Administrative Law Judge recommends that the current language be replaced by the following or similar language: "In order to obtain and maintain the Commissioner's approval as a PT provider for all fields of testing or obtain and maintain the Commissioner's approval to supply PT samples for particular fields of testing, providers must establish and maintain a quality system meeting the requirements of this part," Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2075 substantially different than originally proposed.

Minn. R. 4740.2099, item C (page 66, lines 20-22)

As written, item C states, "Failure to demonstrate the capability of an analyst **may** result in suspension of certification for that field of testing." (Emphasis added.) This language is vague and vests unlimited discretion in the Commissioner. Because an earlier rule part (4740.2050, subp. 9, item B(5)) already notifies regulated parties that the grounds for suspension of certification include "failure of the laboratory to maintain records that demonstrate the capability of laboratory staff as required by 4740.2099," the agency may, if it wishes, remedy this defect by deleting this sentence from item C of part 4740.2099. However, if the agency wishes to emphasize this point in part 4740.2099 as well, the defect can be corrected by replacing the language at issue with the following (or similar) language: "Failure to maintain records that demonstrate the capability of laboratory staff as required in this part is grounds for suspension of certification under part 4740.2050, subpart 9." The proposed language parallels the language of 4740.2050, subp. 9, item B(5), and ensures consistency in the rules. Changing the proposed language in accordance with the recommendation of the Administrative Law Judge is needed and reasonable, and will not make rule part 4740.2099 substantially different than originally proposed.

Minn. R. 4740.2100, subp. 9, item E (page 77, lines 22-24)

The rule as written states in item E that "[a] laboratory must document acceptance criteria for mass spectral tuning. The criteria are subject to the approval of the commissioner." No further information is given in the rule about this topic.

Because the language of the rule part does not specify the criteria that the Commissioner will consider when determining whether to approve a laboratory's acceptance criteria, the rule is vague, fails to provide regulated parties with fair notice of what will be expected, and gives the Commissioner undue discretion in making such determinations. To correct this defect, the agency must amend the language to refer to criteria or standards that will be used in evaluating acceptance criteria. Changing the proposed language in this manner is needed and reasonable, and will not make rule part 4740.2100 substantially different than originally proposed.

Recommended Technical Corrections

The following discussion does not relate to defects in the rules, but merely outlines recommendations for clarification to the rules that the Department may adopt if it chooses to do so. In each instance, adoption of the suggested approach would be needed and reasonable and would not make the rule part substantially different than the rule as originally proposed.

Minn. R. 4740.2010, subp. 1 (page 2, lines 4-12)

The current rule language states that the terms used in parts 4740.2050 to 4740.2120 have the meanings given to them in the rule and in chapters 1 through 6 of the National Environmental Laboratory Accreditation Conference (NELAC) Standards, which are incorporated by reference. The proposed rules merely provide an Internet address for the NELAC standards. Under Minn. Stat. § 14.07, subd. 4, the Revisor's certification that the form of the rule is approved reflects the Revisor's finding that the publication incorporated by reference is conveniently available to the public. If possible, however, the agency should consider adding to the rule information about other ways to locate the NELAC Standards to ensure availability to those who may lack easy Internet access.

Minn. R. 4740.2010, subp. 55 (page 10, lines 21-25)

The proposed rule defines "standard" in part to mean "the certified reference materials produced by the U.S. National Institute of Standards and Technology or other equivalent organization," but does not give information concerning where these materials can be found. The agency should consider adding further information to the rule to ensure that those regulated by these rules can readily access these materials.

Minn. R. 4740.2050, subp. 6, item C (page 16, lines 17-20)

The Administrative Law Judge proposes the following change to this language regarding laboratory inspections: "When the commissioner determines after inspection that a certified laboratory does not comply with applicable provisions of parts 4740.2010 to 4740.2120, the commissioner shall notify the laboratory of the deficiencies in writing." This recommended change provides clarification to the laboratories that any deficiencies found during an inspection by the Department will be provided to the laboratory in writing and not merely orally.

Minn. R. 4740.2050, subp. 6, item E (page 17, lines 10-12)

The Administrative Law Judge proposes the following change to this language regarding laboratory inspections: "With ~~the~~ its new application, the laboratory must submit written documentation of the steps taken to correct the deficiencies ~~with its new application~~." This recommended change merely corrects a redundancy in the proposed rules.

Minn. R. 4740.2050, subp. 10, item A (page 21, lines 5-7)

The Administrative Law Judge proposes the following change to the language regarding revocation of laboratory certification: "~~A laboratory's certification may be revoked in total or in part through written notification by the commissioner.~~ When the commissioner determines that there are grounds for partial or total revocation of a laboratory certification, the commissioner shall notify the laboratory in writing. The laboratory shall retain certification . . . ." The proposed language parallels the suspension language in subpart 9, thereby providing greater clarity and consistency across the rules, and eliminates ambiguity about the Commissioner's discretion in revoking certification.

Minn. R. 4740.2050, subp. 14, item A (page 26, lines 18-22)

The Administrative Law Judge proposes the following change to the language regarding voluntary withdrawal of certification by laboratories: "~~A laboratory may choose to withdraw its application for certification or its current certification in total or in part before the expiration date by notifying the commissioner in writing and specifying the effective date of withdrawal~~. If a laboratory chooses to withdraw its application for certification or its current certification in total or in part, the laboratory shall notify the commissioner in writing and specify the effective date of withdrawal." The proposed language would clarify the rule by eliminating some ambiguity about the process of voluntary withdrawal and whether or not a laboratory seeking to withdraw its certification is required to accomplish withdrawal in writing with an effective date.

Minn. R. 4740.2060, subp. 2, item A and subp. 3, item A (page 30, lines 9 and 26)

It is recommended that the agency consider adding website addresses for these Code of Federal Regulations citations. Such amendments would create consistency across each of the subparts in 4740.2060 and provide greater ease of access to the federal regulations for the readers of the rule.

Minn. R. 4740.2087, subp. 2, item D (4) (page 49, lines 13-14)
Minn. R. 4740.2095, item C (14) (page 63, lines 13-15)

The Administrative Law Judge recommends that the Department consider revising these two rule parts (as well as any other references to signatures that are contained in this set of rules) to make it clear whether the Department will in all circumstances accept electronic signatures on documents filed by the laboratories. This will clarify the agency's intent and result in additional consistency in the rules.

Minn. R. 4740.2091, subp. 3, item F (page 55, line 4)

The Administrative Law Judge proposes the following minor change to this language regarding frequency of calibration equipment: ". . . all thermometers must be calibrated on an annual basis against ~~an~~ a NIST thermometer." This recommended change merely corrects a grammatical error.

Minn. R. 4740.2120, subp. 10, item B (page 94, line 6)

The agency may wish to change this language to state that "background radiation measurement values ~~are~~ must be subtracted from the total measured activity in the determination of the sample activity." This recommended change would parallel the language used in the other items contained in this subpart of the proposed rule.

B.L.N.